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Comparison of Ankle–Brachial Index Measured by an Automated Oscillometric Apparatus with that by Standard Doppler Technique in Vascular Patients

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Abstract *Objectives:* To evaluate the determination of ankle–brachial indices (ABIs) using a simple automated ankle pressure measurement device in comparison with the Doppler technique.
Design: ABI was measured in 61 patients (122 legs) admitted to the department of vascular surgery, Rigshospitalet. ABI was calculated twice using both the methods on both legs.
Materials and methods: We tested the automated oscillometric blood pressure device, CASMED 740, for measuring ankle and arm blood pressure and compared it with the current gold standard, the hand-held Doppler technique, by the Bland–Altman analysis.
Results: Using the Doppler-derived ABI as the gold standard, the sensitivity and specificity of the oscillometric method for determining an ABI ≤ 0.9 is 71% and 92%, respectively. The overall accuracy for correctly identifying an ABI of 0.9 with the oscillometric method was 82%. Ankle pressures measured by CASMED 740 were systematically higher in patients with reduced ankle pressures, but accurate in patients with ankle pressures above 90 mm Hg.
Conclusion: Automated oscillometric assessment of ankle blood pressure and ABI may falsely categorise PAD patients as having a normal ankle pressure and ABI.

Ankle–brachial index (ABI) is a reliable method for assessment of the severity of lower limb ischaemia.[1] Population studies have consistently shown that an ABI below 0.9 is associated with an increased risk of cardiovascular disease and all-cause mortality with hazard ratios between 1.9 and 3.3.[2] Recent guidelines[3,4] recognise reduced ABI as an independent risk factor. Measurement of ABI using a hand-held Doppler technique is an inexpensive and reliable method,[1] hence ABI can be considered a screening tool to identify high risk elderly population. However, there is a learning period and the method demands ongoing practice if accurate results are to be obtained. Therefore, an automated oscillometric blood pressure apparatus could be beneficial. In a recent study, the CASMED 740 apparatus was

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shown to obtain reliable results in people with a predominantly normal ABI.[5] We evaluated if the CASMED 740 automated oscillometric blood pressure apparatus could provide accurate measurements at the ankle level to calculate ABI in patients with various types of vascular disease. We tested the reproducibility of the measurement and compared it to the ABI derived using the hand-held Doppler method.

Methods

The study material included 61 patients admitted for surgical treatment or evaluation of venous disease to the department of vascular surgery, Rigshospitalet, the University of Copenhagen. Inclusion criteria were patients suffering from venous disease ($n = 8$), abdominal aneurysmal disease (AAA) ($n = 12$), carotid stenosis ($n = 1$) and symptomatic peripheral arterial disease (PAD) ($n = 43$) (symptoms of claudication or critical ischaemia); two patients with AAA and one with carotid stenosis also had PAD. Exclusion criteria were renal insufficiency defined by creatinine levels above 150 m mol/l, haemodialysis, known diabetic medial sclerosis, lower as upper extremity circumference below 24 cm and above 34 cm in width, respectively. Informed consent was obtained from all the participating patients.

We measured the ABIs of both lower limbs using an automated oscillometric device, CASMED 740 (Casmedical Systems Inc. Branford, Connecticut, USA), with a 14×37.5 cm cuff width and with hand-held Parks 811-B continuous wave 8—9.7 MHz Doppler ultrasound pencil probe (a quarter inch) using a sphygmomanometer with a 12×35 cm cuff width. The two methods were calibrated according to the manufacturer's recommendations.

Procedure

With the patient in a supine position and after 10 min of rest, the brachial systolic pressure was measured on both arms by the appearance of the pulse sound registered by the Doppler at the brachial artery as the cuff was deflated. Doppler-measured ankle pressures were performed at the dorsalis pedis and posterior tibial artery. The highest ankle pressure was used for calculating the ABI.

After measuring pressures using the Doppler technique, bilateral arm blood pressures followed by bilateral ankle pressures were measured using the oscillometric method (CASMED 740).

All measurements using the oscillometric as well as the Doppler methods were performed by the same investigator experienced in using both the techniques for measuring blood pressure.

ABIs were calculated after collection of all data. We used the ratio of the highest registered measurements of ankle and brachial blood pressures.[1]

To test for reproducibility, 10 patients were investigated twice. In all 10 patients, the ABI was determined on both legs using both the techniques in 5 min time intervals. The variability of each method was determined as described by Bland and Altman,[6] and the standard variation in the ABI mean differences between the two methods was determined as 0.12.

Power calculations were performed from the following presumptions: we defined the clinical relevant difference in ABI as 0.15, calculated a standardised difference of 1.2, set the power to 0.9 and alpha to 0.01. Using the Altman nomogram[7] for sample size calculation, the required size was 23 patients or 46 legs. We tested both the methods in an additional 51 patients to avoid under-powering of the sample size; hence a total of 61 patients (including those 10 patients from reproducibility test) and 122 legs were investigated.

Statistical analyses were performed using STATA version 10.0 and SPSS version 15.0.01. Reproducibility and comparison of the two methods were investigated as described by Bland and Altman.[6] Limits of agreements are defined as the 95% confidence interval of the mean difference between the two measurements. Pitman's test of variance was applied to check for a difference in the double determinations. Accuracy of the oscillometric methods of estimating an ABI ≤ 0.9 measured using Doppler was assessed with receiver operating curve statistics. Analysis of variance (ANOVA) corrected for multiple testing with Bonferroni adjustment. A two-sided p-value of less than 0.05 was considered significant.

Results

Sixty-one patients admitted to the department of vascular surgery had bilateral ankle pressures measured using both the methods (122 legs). The median patient age was 67 years (inter quartile range 63—74 years). Fifteen patients had diabetes. The reasons for hospitalisation surgical treatment or evaluation of venous disease ($n = 8$), abdominal aneurysmal disease (AAA) ($n = 12$), carotid stenosis ($n = 1$) and symptomatic peripheral arterial disease (PAD) ($n = 43$) (symptoms of claudication or critical ischaemia); two patients with AAA and one with carotid stenosis as well as PAD.

Reproducibility of each method

Fig. 1 illustrates the Bland—Altman plot for 10 patients (20 limbs) investigated twice with each method. For the Doppler ABI method, the mean difference between measurements was 0.0055 with ± 0.11 limits of agreements (Pitman's test of variance: $p = 0.97$). The CASMED 740 ABI method had a mean difference between measurements of -0.001 with ± 0.14 limits of agreements (Pitman's test of variance: $p = 0.97$), thus confirming that both methods were equally reproducible.

Comparison of the two methods

Fig. 2 (top) shows the scatter plot of ABI measured by CASMED 740 as a function of that measured by Doppler. By linear regression, ABI measured by CASMED 740 was equal to 0.41+ (Doppler ABI * 0.61). The Bland—Altman plot (Fig. 2 (bottom)) shows a mean ABI difference of 0.08 with limits of agreements between 0.29 and -0.29 (Pitman's test of variance: $p < 0.001$). If linear regression is analysed with the 'difference in ABIs' as a function of the 'average ABI', a negative linear function is obtained (difference ABI = 0.35 * ((-0.31)* average ABI)).

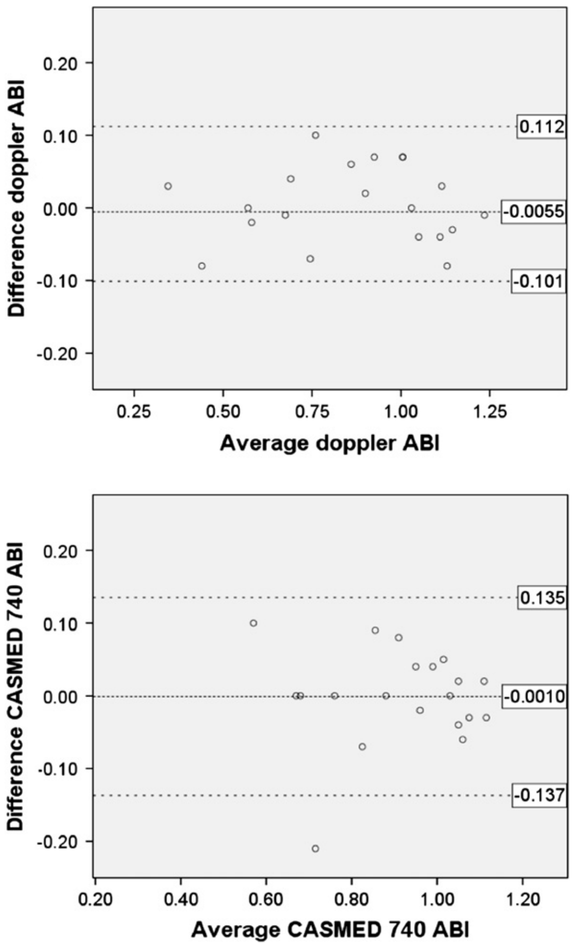

Figure 1 For calculation of power: Bland—Altman plot of the initial 20 ABI measurements obtained by Doppler (top) and by CASMED 740 (bottom), showing equal reproducibility.

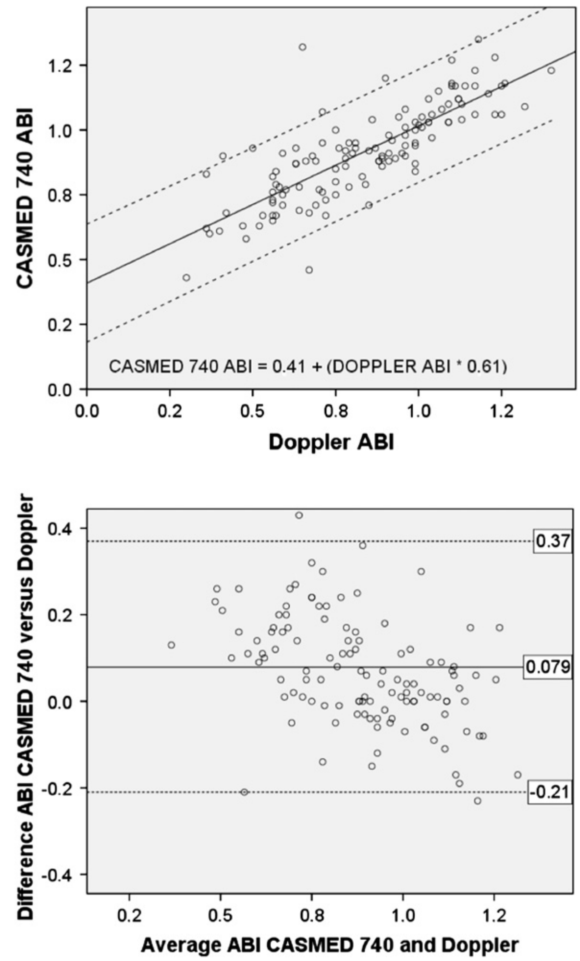

Figure 2 Top: Scatter plot of ABI measurement by CASMED 740 versus ABI measurement by Doppler. The line show the best linear regression with 95% confidence interval. Bottom: Bland-Altman plot of the difference between CASMED 740 and Doppler ABI measurement of 122 legs as a function of the average of the two methods. In both graphs the dotted line indicate 95% confidence interval. Circles in both graphs symbolize each measurement. All values in both *X* and *Y* axis's are ABI index.

A comparison of the arm and ankle pressures measured by both the methods and the Bland—Altman plot of these measurements are shown in Fig. 3. The ankle pressures measured by the CASMED 740 apparatus were systematically higher as compared to the standard Doppler method in patients with low ankle pressures. Plotting the 95% percentiles of the difference in ankle pressures of the two methods as a function of the ankle pressure obtained by the Doppler method, we found that the lower the ankle pressures as measured by Doppler, the greater the overestimation by the oscillometric method (Fig. 4). From Fig. 4 it can be derived that when the ankle blood pressure measured with Doppler falls below 90 mm Hg, the difference between Doppler and CASMED 740 measurements increases and becomes statistically different compared to that of the reference group of 111—130 mm Hg in which the measurement obtained by the two methods are most equal.

Accuracy of the oscillometric method

Using the Doppler-derived ABI as the gold standard, the sensitivity and specificity of the oscillometric method for determining an ABI ≤ 0.9 is 71% and 92%, respectively, with an area under the curve of 0.92 (95% CI: 0.87—0.97) (Fig. 5).

The overall accuracy for correctly identifying an ABI of 0.9 with the oscillometric method was 82%.

Discussion

A recent study documented the Doppler technique to be reproducible and accurate when measuring ABI in PAD patients.[8] Another recent study by Beckman et al.[5] assessed the accuracy of the CASMED 740 in 173 patients, of which 118 had a normal ABI. This study, where the oscillometrically derived ABIs were compared to those measured by the Doppler method, found that CASMED 740 had an acceptable accuracy for clinical practice. The mean bias was reported to be 0.04—0.06 ABI with a 95% confidence interval of the mean of ± 0.01.[5] However, Beckman et al. did not incorporate the limits of agreements (95% confidence interval of the sample) in their assessments, which

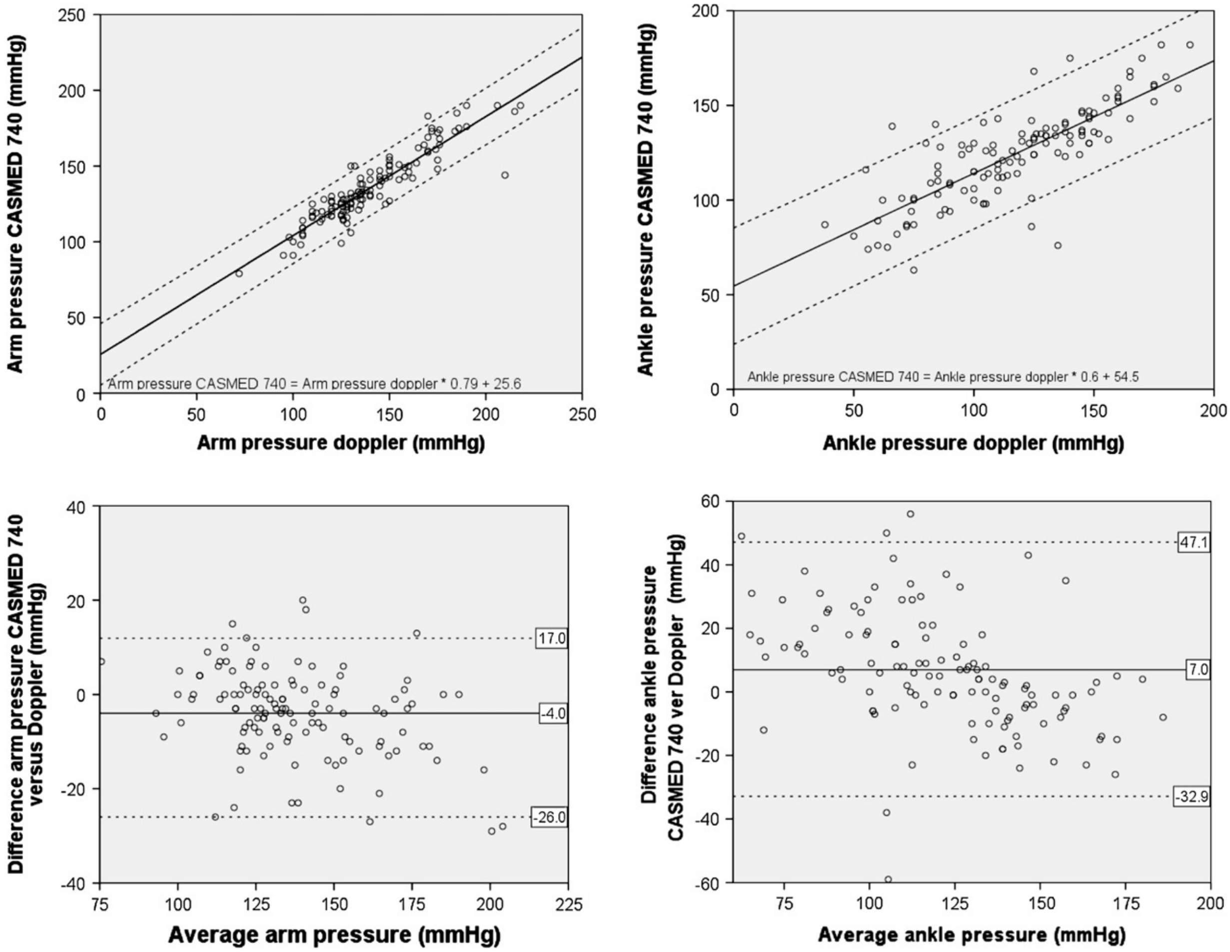

Figure 3 Left column: Top, scatter plot of the arm pressure in mmHg measured with CASMED 740 versus arm pressure measured with Doppler. The line show the best linear regression with 95% confidence interval. Bottom: Bland-Altman plot of the difference between CASMED 740 and Doppler arm pressure measurement (mm Hg) of 122 arms as a function of the average of the two methods. In both graphs the dotted line indicate 95% confidence interval. Right column: Top, scatter plot of the ankle pressure in mmHg measured with CASMED 740 versus ankle pressure in mmHg measured with Doppler. The line show the best linear regression with 95% confidence interval. Bottom: Bland-Altman plot of the difference between CASMED 740 and Doppler ankle pressure measurement (mm Hg) of 122 legs as a function of the average of the two methods (Number given as index). In both graphs the dotted line indicate 95% confidence interval. Circles in both graphs symbolize each measurement.

were found to be approximately ± 0.25 ABI. In our study, we found a similar mean bias of 0.09 with limits of agreements at ± 0.29 ABI. In contrast to the Beckman et al.[5] results, we emphasise the finding of a systematic overestimation of the ankle pressure in patients with low ankle pressures when measured with the oscillometric methods. Fig. 2 (top) illustrates that there is a systematic tendency to overestimate ABI when the values are low, which was confirmed by a linear regression made in the Bland—Altman plot (Fig. 2 (bottom)). If actual pressures are analysed instead of ABI, Fig. 4 reveals that the oscillometric method systematically overestimates low pressures, especially if ankle pressures decline below 90 mm Hg. This tendency was observed in the data obtained by the study of Beckman et al.[5] Other studies have also evaluated various oscillometric devices[9—12] and have tested if the ankle blood pressure obtained by oscillometric method could be used for PAD screening. They have all found difficulties in measuring ankle blood pressure when pressures were below 70 mm Hg, and they reported further that it was impossible to obtain a measurement in 20—33% of legs.[9—12] Thus, if ABI measured by oscillometric methods is recommended for screening of PAD in a high risk population, 29% would incorrectly be classified as normal (sensitivity of 71%) and only 82% (accuracy) would be correctly identified as having a reduced ABI below 0.9, which is lesser than the 88% sensitivity reported by Beckman et al.[5] The explanation is most likely that our study comprised 70% with reduced ankle pressure whereas, in the study of Beckman et al.,[5] only 32% had reduced ankle pressures.

Earlier studies have confirmed the accuracy of automated oscillometric method for measurement of brachial blood pressure,[13] as well as both ankle and brachial pressures in the healthy patients (ABI > 0.9). However, the accuracy of this method in case of reduced arm blood pressure is yet unclear. The discrepancy observed between

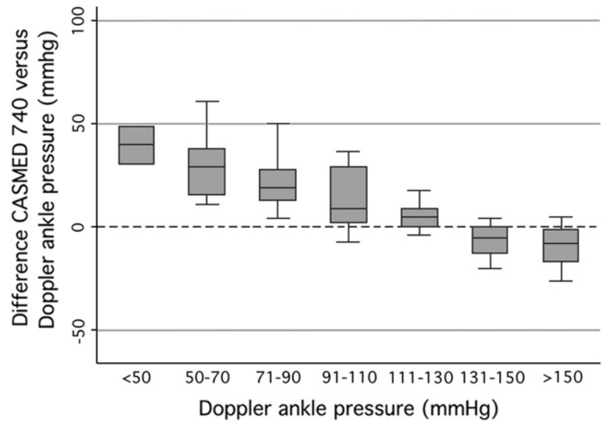

Figure 4 Difference between ankle pressures measured with CASMED 740 and Doppler in mmHg (*Y*-axis), as a function of ankle pressure (mm Hg) obtained with Doppler. Measurements are divided in 7 groups according to ankle pressure (mm Hg) in interval of 20 mm Hg. Box plot, line indicate median, % percentiles, and outer markers 5 and 95% percentiles.

the Doppler and oscilliometric measurements in ankle blood pressure with low values may be because the oscilliometric method measures the mean arterial blood pressure and derives the systolic and diastolic pressures based on manufacturer-dependent mathematical calculations. In particular, obtaining low mean pressures in the lower leg could theoretically be difficult because bones prevent optimal transmission of the mean pressure, leading to inaccurately derived systolic pressures.

Limitations

This study is mainly limited in the small number of patients investigated and the fact that all the patients had either venous or arterial disease. Nevertheless, to overcome this, the apparatus was tested in both normal and, more importantly, also in the extreme situations, where results could lead to changes in medical treatment and intervention. All measurements were conducted such that the ankle

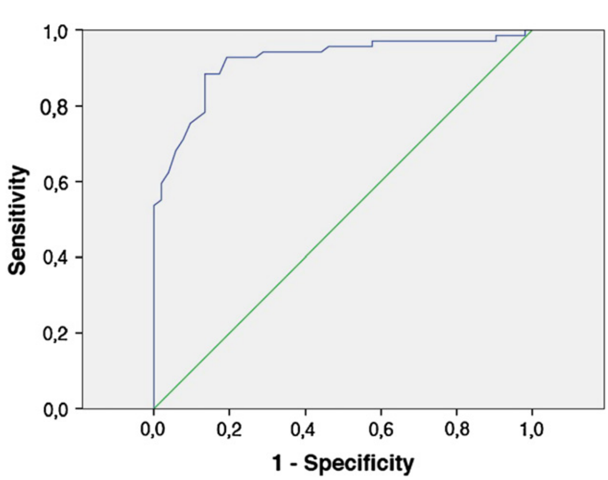

Figure 5 Receiver operating curve for determination of ankle brachial index $\leq$0.9.

blood pressure was always measured first with Doppler, and then with CASMED 740. This could lead to biased results, because, in some patients, 10 min may not enough to induce haemodynamic stability. However, since pressure was always measured first with Doppler, this would have led to a systematically increased Doppler pressure, why the found difference between the methods is the minimal difference which will be seen.

Conclusion

PAD is an under-diagnosed condition and early adjustments to lifestyle, blood pressure and statin treatment may postpone the progression of atherosclerotic arterial disease, and may, more importantly, prevent major cardiovascular events. Therefore, the accuracy of the oscillometric method found in this study is inadequate for measurement of ABI in clinical practice and cannot replace the hand-held Doppler method for measurement of ankle blood pressure at present.

Perspectives

Automated oscillometric ankle pressure, measured with CASMED 740, systematically overestimate ankle pressure in cases with low ankle pressure. Thus, patients are falsely categorised as having a normal ABI. This could prevent undiagnosed, vulnerable, atherosclerotic patients from receiving preventive medical therapy.

Source of Funding

None.

Conflicts of Interest

None.

Disclosures

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